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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,111	03/02/2004	Richard Cornelius	21747-304	3780
37374	7590	12/27/2005		
INSKEEP INTELLECTUAL PROPERTY GROUP, INC 2281 W. 190TH STREET SUITE 200 TORRANCE, CA 90504			EXAMINER VRETTAKOS, PETER J	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/792,111

Applicant(s)

CORNELIUS ET AL.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30 and 37-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-30 and 37-50 is/are rejected.
- 7) ☒ Claim(s) 51-55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claims 24-30, 37-50 and newly added claims 51-55 are examined below.

New art (Thompson et al. (6,152,920)) is presented to address the amendments dated 9-15-05. The action is final.

Note: Applicant's figure 24b best depicts the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 24,25,37,38,43, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. (6,152,920).

Independent claims 24, 37, and 43 (all parentheticals refer to Thompson et al. (6,152,920))

24. A positioning device for an ablation tool (figure 3) comprising:

a flexible elongated tube (14);

a sheath (24) movable back and forth along said elongated tube;

at least two expandable electrode arms (34,36);

a flexible conforming strip (38) extending between said at least two expandable

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electrode arms (depicted in figure 3), said flexible conforming strip being more flexible than each of said at least two expandable electrode arms (col. 9:51-56, the patent discloses decreasing stiffness/increasing flexibility moving distally along operative element 12 including 34,36, and 38);

said flexible conforming strip having sufficient flexibility so as to substantially readily conform to the shape of a target ablation site upon contact of said conforming strip with said target ablation site (see figure 5);

and an ablation mechanism (54) included on said conforming strip.

Note: nothing in the Applicant's claims precludes the designation of operative element 12 as being comprised of "two expandable arms" – 34,36 and a "conforming strip" 38.

Therefore, the potential argument from the Applicant that *element 12 is continuous and that 34,36, and 38 are mere regions prevents the above designation*, is not valid.

37. A method of positioning an ablation device within a body comprising:

providing an ablation tool (figure 3) having an elongated body (inferred by the break adjacent the handle 26) and a flexible electrode (38 including 54) disposed between at least two arm members (34, 36) on a distal end of said ablation tool, said flexible electrode being more flexible than said at least two arm members (col. 9:51-56, the patent discloses decreasing stiffness/increasing flexibility moving distally along operative element 12 including 34,36, and 38);

directing said distal end of said ablation tool to a target tissue area within said body (pulmonary vein, figure 5);
expanding (inferred by the structural differences seen in figures 4 and 5) said flexible electrode;
contacting said flexible electrode to substantially conform to a surface of said target tissue area (pulmonary vein, figure 5);
ablating (col. 15: 43-46) at least a surface of said target tissue area.

43. An ablation positioning device (figures 3,5) for ablating target tissue comprising:
an elongated member (14) sized and shaped to be positioned within the lumen (heart, pulmonary vein) of a body, said elongate member including a distal end (12);
a first arm member (34) disposed on said distal end of said elongated member;
a second arm member (36) disposed on said distal end of said elongated member; and
a flexible ablation member (38) extending between said first arm member and said second arm member, said flexible ablation member being more flexible (col. 9:51-56, the patent discloses decreasing stiffness/increasing flexibility moving distally along operative element 12 including 34,36, and 38) than said first arm member and said second arm member;
wherein said flexible ablation member is conformable (figure 5) to at least a part of a shape of said target tissue (pulmonary vein) and to ablate (col. 15: 43-46) at least a part of said target tissue.

Dependent claims

25. A positioning device according to claim 24, wherein said flexible conforming strip comprises a conforming electrode strip (38 with 54; col. 9:47-49).

38. The method of claim 37 wherein providing an ablation tool includes providing a flexible electrode (38 with 54) that has at least two arm members (34,36) configured to expand (see figure 4 then figure 5) said flexible electrode.

44. The ablation positioning device of claim 43 wherein said flexible ablation member includes an electrode strip (38 includes 54, col. 9:47-49).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 26-30, 39, 41-42 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (6,152,920) in view of Jahns et al. (6,558,382).

Thompson et al. (6,152,920) neglects to expressly disclose electrode needles for tissue fixation.

Jahns discloses in an analogous device (512, figure 5; col. 9:44-60), bipolar needle electrodes (figure 5, 522) to improve connection to the targeted tissue. The Office contends that that placing the Jahns needle electrodes onto the electrode strip (col. 9:47-49) in Thompson et al. (6,152,920) would have been obvious. The placement of Jahns' needle electrodes onto a flat electrode described in Thompson et al. (6,152,920) would yield a very similar device to that seen in the Applicant's figures 23b and 23c, which best depicts the claimed invention.

Note that Thompson discloses **bi-polar** electrodes (col. 18:30-31).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Thompson et al. (6,152,920) in view of Jahns by including Jahns bipolar needle electrodes onto the conforming electrode member in Thompson et al. (6,152,920). The **motivation** would be to improve targeted tissue contact.

Dependent claims (parentheticals refer to Jahns unless stated otherwise)

26. A positioning device according to claim 24, wherein a plurality of ablation electrode needles (522) are disposed on said conforming strip (See Jahns figure 5).

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27. A positioning device according to claim 24, wherein a plurality of bi-polar ablation electrode needles (col. 9:48) are disposed on said conforming strip.

28. A positioning device according to claim 24, wherein each of said at least two expandable arms include a distal tip, wherein a tissue fixation needle is disposed on said distal tip of at least one of said expandable arms (obvious with the substitution of Jahns needles onto the flat/strip Thompson et al. (6,152,920) electrode disclosed in col. 9:47-49).

29. A positioning device according to claim 28, wherein a tissue formation needle is disposed on said distal tip of each of said expandable arms (obvious with the substitution of Jahns needles onto the flat Thompson et al. (6,152,920) electrode).

30. A positioning device according to claim 24, wherein one anchoring needle (522) is disposed on said flexible conforming strip.

39. The method of claim 38 wherein the providing of a flexible electrode includes providing a tissue fixation needle (522) on a distal tip of at least one of said at least two arm members (obvious with the substitution of Jahns needles onto the flat Thompson et al. (6,152,920) electrode).

41. The method of claim 37 wherein the providing of a flexible electrode includes providing a plurality of ablation electrode needles (522) on said flexible electrode.

42. The method of claim 37 wherein the providing of a flexible electrode includes providing a plurality of bipolar ablation electrode needles (col. 9:48) on said flexible electrode.

45. The ablation positioning device of claim 43 wherein a plurality of electrode needles (522) are disposed on a surface of said flexible ablation member.

46. The ablation positioning device of claim 43 wherein a plurality of bipolar electrode (col. 9:48) needles are disposed on said flexible ablation member.

47. The ablation positioning device of claim 43 wherein said first arm member includes a tissue fixation needle disposed on a distal tip of said first arm member (obvious with the substitution of Jahns needles onto the flat Thompson et al. (6,152,920) electrode).

3. Claims 40 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (6,152,920) in view of Jahns et al. (6,558,382) and further in view of Lundkvist et al. (6,625,486).

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Neither Jahns not Thompson et al. (6,152,920) expressly disclose retractable needle electrodes.

Lundkvist discloses a catheter with retractable needle electrodes (12, figures 2 and 2b). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Thompson et al. (6,152,920) in view of Jahns and further in view of Lundkvist by including retractable needle electrodes onto the conforming electrode member in Thompson et al. (6,152,920). The motivation would be to prevent needle electrodes from causing luminal irritation as disclosed in Lundkvist col. 6:44-48.

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

Note: the Applicant has obviated the prior 35 USC § 112 rejection through the clarification provided in the Amendment dated 9-15-05 regarding the difference in the application between "expandable" and "retractable" electrode arms.

Allowable Subject Matter

Claims 51-55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art neglects to disclose the "walking" process described in claim 51.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
December 20, 2005



MICHAEL PEFFLEY
PRIMARY EXAMINER